

Remarks

Request for Non-Entry of Unentered Amendment:

The Attorney for the Applicants requests non-entry of the unentered amendment filed on November 28, 2007.

Cancellation and Amendment of Claims

In light of the Examiner's remarks and rejections, particularly those in the Final Office Action of October 3, 2007 and in view of the Advisory Action of January 9, 2008, in addition to those claims cancelled earlier, the Applicants' Attorney has herein cancelled claims 99 and 100 and amended claim 64. The cancellations and amendment are based upon the last-entered amendment in the present case, dated July 16, 2007.

The Applicants respectfully request the Examiner's review of the amended Claim.

In support of the assertion that the remaining Claim is now in condition for allowance, the Attorney for the Applicants offers the following remarks and responses:

1. Rejection under 35 USC 112, second paragraph: Indefiniteness:

Claims 64 had been rejected as noted. The Applicants' Attorney acknowledges the withdrawal of the rejection as to Claim 64.

2. Rejection under 35 USC 112, first paragraph: Written Description:

In response to the rejection of claims 64 and 99 – 100 in the Final Office Action under 35 USC 112, first paragraph, Written Description, and in view of the remarks in the Advisory Action, the Attorney for the Applicants has, herein, cancelled Claims 99

and 100 and amended Claim 64 in an effort to address the rejections in the Final Office Action and also the remarks in the Continuation Sheets of the Advisory Action. As follows, the Attorney for the Applicants respectfully submits that the claims are now in condition for allowance.

The Attorney for the Applicants respectfully requests the Examiner's consideration that the rejection to Claim 64 under 35 USC 112, first paragraph, written description is rendered moot by the amendment herein. Further, the Attorney seeks the Examiner's acknowledgment that the rejections of Claims 99 and 100 are moot in view of the cancellation of said Claims.

The amendment of Claim 64 specifies that the expression vector is pET15b, which is fully disclosed in the specification (see Examiner's remarks, top of page 5 of the Final Office Action). Further, the peptide extensions are fully disclosed in the specification to include T7B and the "variations of the peptide with amino acid substitutions, but which all maintain a net negative charge of between -2 and -20" (Examiner's remarks bottom of page 5). The amendment herein further identifies that protein or polypeptide of interest as being proteins which, in the absence of fusion with the peptide extensions, would exhibit poor solubility or misfolding. The Attorney for the Applicants submits that the currently amended Claim 64 is fully disclosed in the specification to instruct a person of ordinary skill in the art, and one of ordinary creativity, as to how to make and use the invention herein claimed.

The Examiner points out that "the written description for a genus may be satisfied by sufficient description of a representative number of species by actual

reduction to practice or by disclosure of relevant identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that the applicant was in possession of the claimed invention.” The Attorney for the Applicants submits further that the written description shows that the Applicants were in complete possession of the claimed invention at the time of filing of the application. Through a reduction to practice and structure/function characteristics, the invention as claimed is fully described. As disclosed in the reduction to practice in the specification, the solubility and folding of several proteins (approximately half of those exemplified in the specification) was enhanced by expression in fusion with the peptide extensions of the claimed invention and the common feature(s) of the proteins exemplified are that, in the absence of fusion with the claimed peptides, the proteins were known to be insoluble/misfolded following recombinant expression.

While enhancement of the solubility/folding of only about half of the proteins exemplified was achieved, this outcome would be fully expected by those skilled in the art of over expression in bacteria. If a single fusion partner known in the art was suitable for enhancement of all such normally insoluble/misfolded proteins or polypeptides of interest, there would not be the myriad vectors, each having a different fusion partner, available from the suppliers of such materials and there would be no need to continue to develop such fusion partners. Thus, the outcomes exemplified with the peptide extensions (fusion partners) of the claimed invention are sufficient to support the now quite narrowed genus herein claimed.

3. Rejection under 35 USC 112, first paragraph: Enablement.

The Attorney for the Applicants acknowledges the withdrawal of the rejection of Claim 64 with respect to enablement.

Thus, the Applicants respectfully submit that the Claim presented herein is supported in full by the written description and therefore request reconsideration and withdrawal of the rejection.

Summary

Claims remaining under consideration include currently amended Claim 64. The amendments contain no new matter.

In light of the above Amendments and Remarks, applicants respectfully submit that the instant application is now in condition for allowance and solicit a timely notice of allowance.

Respectfully submitted,



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